

SIRTeX

SIR-Spheres®
Y-90 resin microspheres

2025 Reimbursement Guide: OFFICE-BASED LAB

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What is Selective Internal Radiation Therapy (SIRT)

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a liver-directed therapy and is typically a two-stage process – the work-up and the treatment.

It requires the involvement of a multidisciplinary team consisting of representatives from most, if not all, of the following specialties: Medical Oncology, Surgical Oncology, Gastroenterology / Hepatology, Nuclear Medicine, Interventional Radiology/Oncology, and Radiation Safety.

SIRT targets liver tumors directly with locally applied radiation, while sparing healthy liver tissue, by using the special tumor's blood supply.

Healthy liver tissue derives about two-thirds of its blood from the portal vein, with one-fifth to one-third of the blood coming from the hepatic artery.

In contrast, liver tumors derive up to 90% of their blood from the hepatic artery, since they need a profuse supply of highly oxygenated blood. The hepatic artery therefore provides an ideal channel for a targeted tumor treatment.

What are SIR-Spheres® Y-90 resin microspheres

SIR-Spheres® Y-90 resin microspheres are microscopic spheres that are delivered via SIRT to liver tumors. The polymer microspheres with an average diameter of approximately 32.5 microns, are loaded with yttrium-90 (Y-90). After administration to the hepatic artery, SIR-Spheres Y-90 resin microspheres lodge preferentially in the vasculature of the tumor. The beta radiation remains localized, penetrating a mean of 2.5 mm in the tissue, destroying the tumor cells. Due to the half-life of 64.1 hours, most radiation (94%) is delivered in 11 days. The microspheres are biologically inert and are not metabolized or excreted. Each vial is for a single patient use.

SIR-Spheres Y-90 resin microspheres are the ONLY fully FDA PMA-approved yttrium-90 microspheres for the treatment of HCC and mCRC in the liver.^{1,2,3} backed by prospective clinical studies. SIR-Spheres Y-90 resin microspheres can be used alone or in combination with chemotherapy.

SIR-Spheres Y-90 resin microspheres are the ONLY yttrium-90 microspheres administered using contrast imaging, ensuring visualization, and confirmation of distribution. Coupled with personalized dosing, and precise infusion, complete procedural control is assured.

Delivered through the hepatic artery, SIR-Spheres Y-90 resin microspheres directly target liver tumors with yttrium-90 beta radiation, minimizing healthy tissue exposure. SIR-Spheres Y-90 resin microspheres have a relatively low density similar to blood, which enhances infusion efficiency, resulting in a homogeneous distribution, that can optimize tumor coverage.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. **Indications for Use:** SIR-Spheres® Y-90 resin microspheres are indicated for the local tumor control of unresectable hepatocellular carcinoma (HCC) in patients with no macrovascular invasion, Child Pugh-A cirrhosis, well-compensated liver function, and good performance status. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Side Effects:** Common side effects are fever, transient decrease of hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious effects due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, acute cholecystitis and radioembolization induced liver disease (REILD). **Consult the Instructions for Use (www.sirtex.com/sir-spheres/risks_adverse-events) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

1. Gray et al. Ann Oncol 2001;12:1711–20.

2. van Hazel et al. J Surg Oncol 2004;88:78–85.

3. Hendlisz et al. J Clin Oncol 2010;28:3687–94.

Diagnostic Indications

ICD-10 CM Diagnosis Codes

Potential Diagnoses

C18.0 – C18.9: Malignant neoplasm of colon

C19: Malignant neoplasm of rectosigmoid junction

C20: Malignant neoplasm of rectum

C22.0: Liver cell carcinoma

C78.7: Secondary malignant neoplasm of liver and intrahepatic bile duct

HCPCS Codes for SIR-Spheres Y-90 resin microspheres

Q3001: Radioelements for Brachytherapy, any type

- Q3001 is billed times 1 unit with the invoice price placed in box 19 of the CMS 1500 form.
- Q3001 is reimbursed by CMS at invoice price and does not have a national CMS rate.
- Q3001 should be used with Medicare Fee For Service claims.

S2095: Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using Y90 microspheres

- S2095 is a BCBSA developed code occasionally used by commercial and Medicare Advantage plans. S2095 is a procedure code.
- S2095 does not have a national CMS rate.

NCCI Edits

CPT descriptors have been shortened for purposes of brevity. See your CPT Guide for full descriptors and coding guidelines.

National Correct Coding Initiative (NCCI) Edits may result in coding conflicts for various treatments and procedures.

Providers should carefully review each quarter's NCCI edit updates. NCCI edits may be downloaded from the CMS website at: <https://www.cms.gov/medicare/coding-billing/ncci-medicare>

Payment Rates

MPFS: The codes and national average payment rates shown are reflective of the Medicare Physician Fee Schedule as outlined in the Calendar Year 2025 Addendum B using 2025 Final MPFS conversion factor (CF) of \$32.3465.

Medicare providers face other cuts known as sequestration (2% reduction) and statutory "Pay-As-You-Go", or PAYGO (4% reduction), due to laws that control federal spending. Although these specific cuts aren't addressed in the MPFS, they could result in a total cut of almost 9% to overall Medicare payments when added to the CF reduction. Congress has acted each year by passing legislation that reduced or eliminated some of these additional cuts and will need to do so again for 2025 payments.

SIR-Spheres Treatment Phases

Patient Evaluation – the patient is assessed after a thorough history and physical as well as blood and diagnostic imaging tests, whether treatment with SIR-Spheres Y-90 resin microspheres is appropriate and if additional preparatory procedures are required. Selective and super-selective vessel assessment via angiography (radiography of vessels after the injection of a radiopaque contrast material via percutaneous insertion of a radiopaque catheter), anatomical imaging, and vascular flow imaging using a diagnostic radioisotope to simulate the administration of SIR-Spheres are performed. If necessary, based on the results, at the time of the evaluation, a coil embolization of any extrahepatic arteries (e.g., gastroduodenal) that would shunt blood flow outside of the treatment target area would be performed.

Treatment Planning – the treating physician and/or other specialists (Medical Physicist or Nuclear Radiologist) interpret the Patient Evaluation phase results and prepare a therapeutic SIRT treatment plan. This phase includes clinical planning, dosimetry calculations, and special medical radiation physics or treatment considerations.

SIR-Spheres Administration – the patient undergoes angiography to confirm there haven't been changes since the Patient Evaluation phase. SIR-Spheres Y-90 resin microspheres are then administered intra-arterially via percutaneous catheter under imaging guidance in accordance with the treatment plan supported by the Written Directive (an authorized user's [the Interventional or Nuclear Radiologist] written order for the administration of material or radiation to a patient).

SIR-Spheres Reimbursement Support Services

Some commercial/private payers including Medicare Advantage plans, and State or Managed Medicaid plans may require providers to obtain a pre-determination or prior authorization for SIR-Spheres Y-90 resin microspheres coverage and related procedures. It is recommended that the coverage policies of your payer mix be researched and that applicable pre-determination requirements be understood PRIOR to treating the patient. Note: Obtaining a pre-determination / prior authorization is not a guarantee of coverage or payment. Coverage and payment determination can only be made at the time a claim is adjudicated.

Should you have any questions, please contact the Predetermination team by phone at 888-4-SIRTEX (474-7839) ext. 717 or email sirtexhelp@sirtex.com.

For questions related to all other reimbursement questions, please contact the US HEPRA team at USReimbursement@Sirtex.com

Phase I: Pre-Treatment

MAPPING

The possible coding options listed in this section are based on Medicare guidelines and society recommendations. Medicare base case coding scenarios typical for one mapping and one treatment in Office-Based Lab (OBL) setting follow this section.

Catheter Placement(s)			
Service		CMS CY25	
Code	Description	RVUs	Rate
36245	Select catheter placement, initial 1st	35.37	\$1,144.70
36246	Select catheter placement, initial 2nd	23.79	\$769.52
36247	Select catheter placement, initial 3rd or more	40.49	\$1,309.71
36248	Select catheter placement, initial 2nd, 3rd & beyond	3.39	\$109.65

Arterial Shunting Coil Embolization (if required)			
Service		CMS CY25	
Code	Description	RVUs	Rate
37242*	Arterial emb or occ, RS&I; arterial other than hem or tumor	199.91	\$6,466.39

*If you are treating a liver tumor (37243) and embolize the gastric artery or gastroduodenal artery as a precaution, on the same day, only code 37243 can be billed, not both 37243 and 37242.

Hepatic Angiogram			
Service		CMS CY25	
Code	Description	RVUs	Rate
75726*	Angiography, visceral, RS&I	5.12	\$165.61
75774**	Angiography, selective, RS&I (each add'l vessel)	2.87	\$92.83

*The ability to bill for angiograms on the same date typically would only be supported when it is diagnostic and separate from the procedure. For example, the following criteria would need to be met: No prior catheter-based angiographic/venographic study is available and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study, **OR** A prior study is available, but as documented in the medical record: The patient's condition with respect to the clinical indication has changed since the prior study, **OR** There is inadequate visualization of the anatomy and/or pathology, **OR** There is a clinical change during the procedure that requires new evaluation outside the target area of intervention. If supported for billing, then modifier 59 modifier should be appended to any diagnostic angiogram (e.g., 75726, 75774) performed with an intervention (e.g., 37242, 37243) to distinguish a separate and distinct service as there are edits with these services.

**The following codes are bundled into the reimbursement for 37242 whether or not coiling is performed.

Volume Imaging Options

Service		CMS CY25	
Code	Description	RVUs	Rate
76376	3D Post Scan, not requiring image post-processing	0.77	\$24.91
76377	3D Post Scan, requiring image post-processing	2.38	\$76.98

CT Acquisition (maybe billed in conjunction with CPT 76377)

Service		CMS CY25	
Code	Description	RVUs	Rate
74170	CT, abdomen; w & w/o contrast	7.89	\$225.21
74175	CTA abdomen w/contrast	9.31	\$301.15

Mapping Options

Service		CMS CY25	
Code	Description	RVUs	Rate
A9540	TC-99m per study dose, up to 10	NA	Contractor priced
78801	Planar imaging of multiple areas	7.32	\$236.78
78803	SPECT, single area in a single day	10.14	\$327.99
78831	SPECT, multiple areas	18.95	\$612.97
78830	SPECT/CT, single area	12.75	\$412.42
78832	SPECT/CT, multiple areas	24.03	\$777.29
78835	Radiopharmaceutical quantification measurement	2.65	\$85.72

Phase I: Pre-Treatment

PLANNING

Office may bill for this code in between the date of the mapping and treatment day but not on the same day as the mapping and treatment. This code is used when a patient requires complex radiation therapy planning as part of their cancer treatment. This includes detailed analysis and calculations to design an effective treatment strategy.

Codes applicable between mapping and treatment

Service		CMS CY25	
Code	Description	RVUs	Rate
77263*	Therapeutic radiology tx plan, complex	5.10	\$164.97

*Use of 77263 requires a written order by the physician. Treatment planning should be billed and dictated separately prior to microspheres administration.

Phase II: SIR-Spheres Y-90 resin microspheres Day of Treatment

PLANNING AND DAY OF TREATMENT

The possible coding options listed in this section are based on Medicare guidelines and society recommendations. Medicare base case coding scenarios typical for one mapping and one treatment in Office-Based Lab (OBL) setting follow this section.

Catheter Placement(s)

Service		CMS CY25	
Code	Description	RVUs	Rate
36247	Select cath place, initial 3rd or more	40.49	\$1,309.71
36248	Select cath place, initial 2nd or more and beyond	3.39	\$109.65

Hepatic Angiogram

Service		CMS CY25	
Code	Description	RVUs	Rate
75726*	Angiography, visceral, RS&I	5.12	\$165.61
75774**	Angiography, selective, RS&I (each add'l vessel)	2.87	\$92.83

*The ability to bill for angiograms on the same date typically would only be supported when it is diagnostic and separate from the procedure. For example, the following criteria would need to be met: No prior catheter-based angiographic/venographic study is available and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study, **OR** A prior study is available, but as documented in the medical record: The patient's condition with respect to the clinical indication has changed since the prior study, **OR** There is inadequate visualization of the anatomy and/or pathology, **OR** There is a clinical change during the procedure that requires new evaluation outside the target area of intervention. If supported for billing, then modifier 59 modifier should be appended to any diagnostic angiogram (e.g., 75726, 75774) performed with an intervention (e.g., 37242, 37243) to distinguish a separate and distinct service as there are edits with these services.

**The following codes are bundled into the reimbursement for 37243 whether or not coiling is performed.

SIR-Spheres® Y-90 Resin Microspheres

Service		CMS CY25	
Code	Description	RVUs	Rate
Q3001 ^{1,2,3}	Brachytherapy Radioelements, any type	NA	Invoice
S2095 ^{4,5}	Transcatheter embo for tumor destruction using Y-90 microspheres	NA	NA

1. Q3001 is billed times 1 unit with the invoice price placed in box 19 of the CMS 1500 form.

2. Q3001 is reimbursed by CMS at invoice price and does not have a national CMS rate.

3. Q3001 should be used with Medicare Fee For Service claims.

4. S2095 is a BCBSA developed code occasionally used by commercial and Medicare Advantage plans. S2095 is a procedure code.

5. S2095 does not have a national CMS rate.

6. S2095 should be billed with modifier 59 when billed on the same day as 37243

Tumor Embolization

Service		CMS CY25	
Code	Description	RVUs	Rate
37243	Vascular emb or occ, includes RS&I, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors	242.41	\$7,841.12

Microspheres Administration: Authorized User Codes (AU)


Service		CMS CY25	
Code	Description	RVUs	Rate
77370 ¹	Special Medical Radiation Physics Consultation	4.50	\$145.56
77470 ²	Special Treatment Procedure	4.40	\$142.32
77300	Basic Dosimetry Calculation	2.02	\$65.34
79445 ³	Radiopharm therapy, intra-arterial particulate admin (1 doctor model (IR/AU)	NA	NA
77778 ⁴	Interstitial rad source application; cplx (2 Doctor model IR w/separate AU)	28.06	\$907.64
77399	Unlisted procedure medical radiation physics, dosimetry (fusion)	NA	Contractor Priced

1. Special Medical Radiation Physics Consultation, use of this code requires a written order by the physician.
2. Special treatment procedure used for brachytherapy and in circumstances requiring extra work over and above basic dosimetry calculation: Patient with previous chemo, receiving concurrent chemo, or external beam radiation to the body/liver. AU must review the current CT scan, liver function studies, and ECOG performance status to determine the % yttrium-90 dose to be adjusted taking into account previous treatments. Often used as a re-treatment code. Should be supported by clinical treatment notes.
3. Do NOT code CPT 79445 for the injection of TC99 MAA on the mapping day as this is considered part of the nuclear medicine exam.
4. The physician will bill either 79445 or 77778, whichever is most appropriate per the physician and role in the procedure. There is a Medicare NCCI edit with 37243 and 77778.

Post Treatment Imaging (Provider Preference)

Service		CMS CY25	
Code	Description	RVUs	Rate
78801	Planar imaging of multiple areas	7.32	\$236.78
78803	SPECT, single area in a single day	10.14	\$327.99
78831	SPECT, multiple areas	18.95	\$612.97
78814	Tumor imaging, PET/CT	NA	Contractor Priced
78830	SPECT/CT, single area	12.75	\$412.42
78832	SPECT/CT, multiple areas	24.03	\$777.29
77295	3D radiotherapy plan (MIM)	14.59	\$471.94

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. **Indications for Use:** SIR-Spheres® Y-90 resin microspheres are indicated for the local tumor control of unresectable hepatocellular carcinoma (HCC) in patients with no macro-vascular invasion, Child Pugh-A cirrhosis, well-compensated liver function, and good performance status. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Warnings / Precautions: Non-Target Delivery of SIR-Spheres Microspheres:** Inadvertent delivery of SIR-Spheres microspheres to extra-hepatic structures such as the esophagus, stomach, duodenum, gallbladder or pancreas may result in radiation injury to these structures. Meticulous angiographic technique must be employed to prevent the non-target delivery of SIR-Spheres microspheres to any extra-hepatic structures. **Radioembolization Induced Liver Disease (REILD):** Delivery of excessive radiation to the normal liver parenchyma may result in REILD. The risk of REILD may also be increased in patients with pre-existing liver disease. Consideration should be given to reducing the prescribed activity of SIR-Spheres microspheres in the following clinical settings: Reduced liver functional reserve due to steatosis, steatohepatitis, hepatitis or cirrhosis, Elevated baseline bilirubin level, Non-selective treatment of small tumor burden (< 5% liver involvement), Small liver volume (< 1.5 L), Prior hepatic resection, Prior liver directed therapy. **Radiation Pneumonitis:** High levels of implanted radiation and/or excessive shunting to the lung may lead to radiation pneumonitis. Limit radiation dose to ≤ 30 Gy per treatment and ≤ 50 Gy cumulatively. **Limited Radiation Dosimetry Planning Precision:** The amount of radiation delivered to HCC targets has been found to differ compared to the amount planned. Similar levels of precision should not be assumed when planning for Y-90 microsphere radiation therapy compared to when planning for external beam radiation therapy. **Side Effects:** Common side effects are fever, transient decrease of hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious effects due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, acute cholecystitis and radioembolization induced liver disease (REILD). **Contraindications:** SIR-Spheres microspheres are contraindicated in any patient who has: portal vein thrombosis, ascites or clinical liver failure, markedly abnormal synthetic and excretory liver function tests (LFTs), such as total bilirubin > 2.0 mg/dL or albumin < 3.0 g/dL, > 20% lung shunting of the hepatic artery blood flow, or > 30 Gy radiation absorbed dose to the lungs for a single treatment, or > 50 Gy cumulative radiation absorbed dose to the lungs if the patient is re-treated, as estimated by the 99mTc MAA scan, pre assessment angiogram that demonstrates abnormal vascular anatomy that would result in significant reflux of microspheres to the stomach, pancreas or bowel and had previous external beam radiation therapy to the liver. **Contraindications for Patients with mCRC:** Disseminated extra-hepatic malignant disease, been treated with capecitabine within the two previous months, or who will be treated with capecitabine at any time following treatment with SIR-Spheres microspheres. **Contraindications for Patients with HCC:** Comorbidities or poor overall health (e.g., ECOG performance status rating > 2) which may make the patient a poor candidate for locoregional radiation treatment, disseminated extra-hepatic malignant disease. **General Information:** SIR-Spheres Y-90 resin microspheres may only be distributed to a duly licensed or accredited facility capable of handling therapeutic medical isotopes. This product is radioactive and should thus be handled in accordance with all applicable standards and regulations. **Consult the Instructions for Use (www.sirtex.com/sir-spheres/risks_adverse-events) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

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